EPA

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 4-01

☒ Original ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment
68-W-11-014	☐ Base ☒ Option Period Number: IV	RD - Primary Review of Product Chemistry, Toxicity, Companion Animal Safety and Efficacy Data

Contractor: SUMMITEC CORPORATION

Specify Section and Paragraph of Contract SOW:

Purpose:
☒ Work Assignment Initiation ☐ Work Assignment Close-Out
☐ Work Assignment Amendment ☐ Incremental Funding
☐ Work Assignment Approval

Periods of Performance: From: Date of CO Signature To: 01/31/2016

Comments:

The estimated level of effort for this work assignment is 4,269 hours.

☐ Superfund

Accounting and Appropriations Data

☐ Non-Superfund

Line	DC (Max 6)	Budget/FYs (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:	Cost/Fee	LOE
Previously Approved		
This Action		
Total		

Work Plan / Cost Estimate Approvals

Contractor WP Dated: Cost/Fee: LOE:

Cumulative Approved: Cost/Fee: LOE:

Work Assignment Manager Name: LaTangila Edwards
(Signature) (Date)
Branch/Mail Code: 7505P
Phone Number: (703) 305-7460
Fax Number:

Project Officer Name: LaTangila Edwards
(Signature) (Date)
Branch/Mail Code: 7505P
Phone Number: (703) 305-7460
Fax Number:

Other Agency Official Name:
(Signature) (Date)
Branch/Mail Code:
Phone Number:
Fax Number:

Contracting Officer Name: Christine Edwards
(Signature) 3/3/2015 (Date)
Branch/Mail Code: 3803R
Phone Number: (202) 564-2182
Fax Number:

Contractor Acknowledgement of Receipt and Approval of Workplan *(Signature and Title)*

Date

Contract EP-W-11-014, Option Year Four
External Peer Review and Technical Support of Pesticide Regulatory Activities

WORK ASSIGNMENT
STATEMENT OF WORK

I. TITLE

WA 4-1, RD - Primary Review of Product Chemistry, Toxicity, Companion Animal Safety, and Efficacy Data

II. WORK ASSIGNMENT MANAGER (WAM)

LaTangila C. Edwards, WA COR
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Technical Expert Task 1 and Task 3:

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John Redden – Alternate Technical Expert
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Task 2:

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2777 South Crystal Drive
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III. PERIOD OF PERFORMANCE

Duration: Date of issuance through January 31, 2016

IV. BACKGROUND

EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and Office of Pesticide Programs (OPP), as required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA-as amended 1996) established procedures for the registration and approval of pesticide products, unless specifically exempted (FIFRA section 25), prior to the manufacture, sale and distribution to ensure that the pesticide poses no serious risks to human health or the environment when used according to its label. OPP is responsible for all registration activities for pesticides, including scientific review and risk-benefits

determinations. OPP evaluates the submitted scientific data, and determines whether the data is adequate for making regulatory decisions.

OPP's review process includes hazard identification, exposure analysis, risk characterization, and risk assessment. Scientific staff prepare Data Evaluation Reports (DERs) summarizing the results of the studies, and document their own interpretations and conclusions in internal memoranda and other risk assessment documents. These documents are subject to peer review, both internal and when novel or especially significant concerns or risks are identified, through the FIFRA Scientific Advisory Panel.

All contractor and sub-contractor personnel assigned to work on this WA must obtain FIFRA security clearance.

V. DESCRIPTION OF WORK

TASK 1: REVIEW AND EVALUATION OF INERT PESTICIDE INGREDIENTS

The contractor will review and evaluate toxicology studies submitted to OPP on pesticide product inert ingredients in support of the establishment of tolerances or exemption from the requirement of a tolerance for inert ingredients.

TASK 2: PRIMARY REVIEW AND EVALUATION OF PRODUCT PERFORMANCE (EFFICACY) DATA
Sub Part A – Efficacy Data Review

The contractor will review and evaluate product performance (efficacy) data.

The contractor reviewers will use OCSPP 810 Series Harmonized Guidelines as guidance for reviewing efficacy studies. These are available on the EPA website at http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series810.htm

OPP will provide guidance on the acceptable levels of product performance and untreated control mortality; a list of representative species for which efficacy data should be submitted; as well as Standardized Operating Procedures (SOPs) to assist the contractor in their review of efficacy studies.

OPP will provide the contractor with a standardized template in MS Word, which provides the reporting format and mandatory instructions for extraction of information from each study together with the reviewer conclusions and recommendations.

TASK 2: PRIMARY REVIEW AND EVALUATION OF PRODUCT PERFORMANCE (EFFICACY) DATA
Sub Part B – Product Performance Guidelines Development

OPP will provide the contractor a list of guidelines and topics to compile and organize all information relevant to EPA review OCSPP 810 Series Product Performance Guidelines development and presentations to Scientific Advisory Panel when required. The contractor shall conduct a state-of-the-science review of literature that includes electronic and hand copy acquisition of published science literature; and collect data on insecticide testing processes, procedures and performance standards from national and international regulatory agencies together with International Public Health and Agricultural Agencies. This review shall characterize test methodologies and science issues related to efficacy,

analyze current testing methodologies and guidelines, and prepare recommendation reports regarding modification of current testing methodologies and guidelines, which will be reviewed by OPP and other experts. These documents shall outline the efficacy testing requirements for insecticides used to control public health and/or wood destroying pests with specific guidance from OPP. The EPA guideline work shall include development of new OPPTS test guidelines for Efficacy Testing and Evaluation.

TASK 3: PRIMARY REVIEW OF SCIENTIFIC DATA
Sub Part A - Companion animal safety toxicology

The contractor will prepare a report which discusses both adult and juvenile safety studies. The main task is to evaluate the study data on its merits in fulfilling the 870.7200 guideline. If the study is found to fulfill the guideline requirement the contractor reviewer will categorize the study as "acceptable". If unanswered questions remain after the review of the data the reviewer will categorize the study as "unacceptable."

The contractor reviewers will use the OCSPP 870 Harmonized Guidelines as the acceptable parameter for each study. These are available on the EPA website at
http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series870.htm

OPP will provide the contractor with a standardized template in MS Word, which provides the reporting format.

TASK 3: PRIMARY REVIEW OF SCIENTIFIC DATA
Sub Part B – Acute toxicology (6 pack)

The contractor will prepare a review on each guideline, usually totaling 6 studies. The main task is to evaluate the study data on its merits in fulfilling the 870.1000 to 870.2600 guidelines. If the study is found to fulfill the guideline requirement the contractor reviewer will categorize the study as "acceptable." If unanswered questions remain after the review of the data the reviewer will categorize the study as "unacceptable."

The contractor reviewers will use the OCSPP 870 Harmonized Guidelines as the acceptable parameter for each study. These are available on the EPA website at
http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series870.htm

OPP will provide the contractor with a standardized template in MS Word, which provides the reporting format.

TASK 3: PRIMARY REVIEW OF SCIENTIFIC DATA.
Sub Part C – Product Chemistry

The contractor will prepare reports on product chemistry. Product chemistry is usually broken down into 2 sub parts. Group A consists of the data on product identity, composition, and analysis; and Group B data are the physical and chemical properties of the pesticide product. The main task is to evaluate the study data on its merits in fulfilling guidelines in 830.1000 through 830.1900 for Group A. and 830.6302 through 830.7950 for Group B. If the study is found to fulfill the guideline requirement the contractor

reviewer will categorize the study as "acceptable". If unanswered questions remain after the review of the data the reviewer will categorize the study as "unacceptable."

The contractor reviewers will use the OCSPP 830 Harmonized Guidelines as the acceptable parameter for each review. These are available on the EPA website at http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series830.htm

OPP will provide the contractor with a standardized template in MS Word, which provides the reporting format.

VI. COMMUNICATION AND TECHNICAL DIRECTION

The EPA's Office of Pesticide Programs/Registration Division (RD) will ship via UPS the data review requests to the contractor, on a bi-weekly basis. Each data review is tracked by a unique tracking number called a MRID number.

Technical direction will be given from time to time by telephone, by email, or other written means.

At any time, the contractor shall notify the Agency (contracting officer, project officer and/or WAM) of any concerns and/or issues related to data review, so that they may be remedied immediately.

VII. DELIVERABLES

The contractor shall review, evaluate, and prepare written reports of toxicology studies, efficacy data, companion animal safety toxicology studies, acute toxicology data, and product chemistry data to include any other supporting documentation related to the evaluations conducted under these task areas. All work performed and submitted to EPA shall conform to EPA standards for QA/QC, and DER formatting.

All deliverables under this WA as well as the original registrant laboratory data shall be submitted via UPS (next day delivery) to the Document Tracking Coordinator (DTC) at the following address:

Linda Mascall
2777 South Crystal Drive
RM 7722
Arlington, VA 22202

Phone: (703) 308-9371

Deliverables shall be presented as electronic files: MS Word (2007) format on CD/DVD. Inside each deliverable package that is shipped a custody receipt shall be placed inside stating the data belongs to RD, the DTC's name and phone number, and actual hours performed per MRID number.

TASK 1 Deliverable: Review and Evaluation of Inert Pesticide Ingredients

The contractor will deliver data evaluation reports (DERs) of its evaluation of the toxicology studies submitted to OPP on pesticide product inert ingredients in support of the establishment of tolerances or exemption from the requirement of a tolerance for inert ingredients.

TASK 2 Deliverable: Primary Review of Efficacy (Product Performance) Data

The contractor will deliver the primary review of an efficacy studies (MRIDs) within timeframe specified by the COR upon receipt of the request and data. All of the MRIDs associated with a single data package should be completed at the same time and delivered together because the data support the same product. The contractor will provide OPP with a summary of their internal primary and secondary review process for efficacy studies. The contractor will provide OPP with the names of the reviewers and their resumes. The list must be updated as reviewers change.

TASK 3 Deliverable: Primary Review of Scientific Data.

The contractor will deliver data evaluation reports (DERs) on companion animal safety toxicology data, acute toxicology data, and product chemistry data submitted by the agency.

CONTRACT Deliverables

As per the contract, the contractor shall provide the Agency with a work plan within 14 days of receipt of the work assignment. The project officer/Contracts Officer Representative (COR) will review the work plan and provide the contractor with any changes/suggestions or revisions, in writing. Work plan approval/disapproval, and revision (if necessary), and the timelines involved, will proceed as stipulated in the contract. The work plan should address (among other subjects as needed) the technical approach, resources, timeline, and due dates for all deliverables.

The contractor shall provide each monthly technical and financial progress report as per the contract. The report shall be submitted on or before the 15th of each month (following the completion of the first reporting period), with a copy provided (preferably by email) to the EPA PO/COR and WA COR. Among other data required, the report shall list each review action completed (finished and delivered) during the reporting period, along with its data package bar code, number of studies, technical labor hours, and staff levels. Of course, these stipulations will not reduce any of the contractual monthly reporting obligations.

Content and format of the monthly technical and financial progress report must be intelligible and must be sufficient to support the Agency's review of invoicing, budget status, and technical progress. To this end, any new reporting needs found may be requested by technical direction to the degree permissible under the Contract.

SPECIFIC SCHEDULE OF DELIVERABLES:

Deliverable	Schedule	Format/Distribution

Acknowledgement of Work Assignment (WA)	5 calendar days after WA is issued by Contracting Officer (CO)	Email acknowledgement to CS, and CORs
Work Plan (WP)	14 calendar days after WA is issued by CO	Email a copy to CS and CORs
Quality Assurance Plan	Same as for the WP	Included with WP
Task 2 Deliverable	75 days after receipt of WA	Mail via UPS to DTC
Task 3 Deliverable		Mail via UPS to DTC
Monthly Progress Report	15th of each month (following completion of 1st reporting period)	Email a copy to CS and CORs
Monthly Invoices	15th of each month (following completion of 1st reporting period)	Email a copy to CS and CORs
Other	As per Contract	As per Contract

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 4-02

☒ Original ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment
EP-W-11-014	02/1/2015 to 01/31/2016 ☐ Base ☒ Option Period Number: IV	Primary Review and Evaluation of Pesticide, Mammalian, Non-Target Organisms Toxicity, Environmental Fate, Toxicity, and Product Chemistry and/or Characterization Data and Creation of Data Evaluation Records (DERs)

Contractor: SUMMITEC CORPORATION

Specify Section and Paragraph of Contract SOW:

Purpose:
☒ Work Assignment Initiation ☐ Work Assignment Close-Out
☐ Work Assignment Amendment ☐ Incremental Funding
☐ Work Assignment Approval

Periods of Performance: From: Date of CO Signature To: 01/31/2016

Comments: The estimated level of effort for this work assignment is 1,047 hours.

☐ Superfund

Accounting and Appropriations Data

☐ Non-Superfund

Line	DC (Max 6)	Budget/FYs (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 02/01/2015 To 01/31/2016	Cost/Fee	LOE
Previously Approved		
This Action		
Total		

Work Plan / Cost Estimate Approvals

Contractor WP Dated: Cost/Fee: LOE:

Cumulative Approved: Cost/Fee: LOE:

Work Assignment Manager Name: Pamela Landis (Signature) (Date)	Branch/Mail Code: 7511P Phone Number: (703) 308-7013 Fax Number:
Project Officer Name: LaTangila Edwards (Signature) (Date)	Branch/Mail Code: 7509P Phone Number: (703) 305-7170 Fax Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: Fax Number:
Contracting Officer Name: Christine Edwards (Signature) 3/2/2015 (Date)	Branch/Mail Code: 3803R Phone Number: (202) 564-2182 Fax Number:

Contractor Acknowledgement of Receipt and Approval of Workplan *(Signature and Title)* | Date

EPA Form 1900-69 (Rev 07-95)

WORK ASSIGNMENT
STATEMENT OF WORK

I. TITLE

WA-4-02 - Primary Review and Evaluation of Pesticide, Mammalian, Non-Target Organisms Toxicity, Environmental Fate, Toxicity, and Product Chemistry and/or Characterization Data and creation of Data Evaluation Records (DERs).

II. WORK ASSIGNMENT MANAGER (WAM)

Pamela Landis
2777 South Crystal Drive
RM S-8344
Arlington, VA 22202
Phone - (703) 308-7013
Fax - (703) 308-7026
Email - landis.pamela@epa.gov

Alternate WAM:
N/A

III. PERIOD OF PERFORMANCE

Duration: February 1, 2015 through January 31, 2016

IV. BACKGROUND

EPA's Office of Pollution Prevention and Toxic Substances (OPPTS) and Office of Pesticide Programs (OPP), as required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA-as amended 1996) established procedures for the registration and approval of pesticide products, unless specifically exempted (FIFRA section 25), prior to the manufacture, sale and distribution to ensure that the pesticide poses no serious risks to human health or the environment when used according to its label. OPP is responsible for all registration activities for pesticides, including scientific review and risk-benefits determinations. OPP evaluates the submitted scientific data, and determines whether the data is adequate for making regulatory decisions.

OPP's review process includes hazard identification, exposure analysis, risk characterization, and risk assessment. Scientific staff prepare Data Evaluation Reports (DERs) summarizing the results of the studies, and document their own interpretations and conclusions in internal memoranda and other risk assessment documents. These documents are subject to peer review, both internal and when novel or especially significant concerns or risks are identified, through the FIFRA Scientific Advisory Panel.

Under Contract EP-W-11-014, the Agency will order such work via this Work Assignment (WA) once issued by the Contracting Officer. All contractor and sub-contractor personnel assigned to work on this WA must obtain FIFRA security clearance.

V. DESCRIPTION OF WORK

The primary objective of this task area (task #4 of PWS) is to evaluate the scientific and technical merit of studies submitted to EPA to support an application for registration of a pesticide product. The contractor shall produce DERs for all studies. The contractor shall provide peer review and other environmental studies support to EPA. Specific protocols for systematic review, documentation, and reporting may be identified by EPA through the technical direction of the WAM, or the contractor may be required to propose protocols for EPA approval.

Studies submitted to OPP for the registration of a pesticide will be forwarded to the contractor. Upon receipt of each assigned study, the contractor shall perform an in-depth examination of the study by a reviewer trained in the appropriate scientific discipline. The contractor's reviewer shall examine the reported results and provide a description of his or her conclusions that summarize the overall significance of the study and provide a concise summary of the study and the results, discussing as appropriate: LD50, LC50, dose levels, No Observable Effects Levels (NOELS), Lowest Observable Effects Levels (LOELs) and significant toxicological and pathological effects. The contractor shall classify each study into the appropriate category: Acceptable or Unacceptable. Further, the agency defines an acceptable study to be a study conducted according to OCSPP guidelines (as per BPPD guidelines and related supplemental or other data review as specified).

The review and evaluation of each study will include analysis of all necessary graphic displays of data, summary tables, and references needed to substantiate technical detail supporting the reviewer's conclusions. The contractor's reviewer shall also identify whether the study was performed in accordance with accepted methodologies as prescribed in EPA's published guidelines and whether the data reported in the studies are reliable for characterizing health hazards and risks to humans and the environment. The results of these detailed analyses shall be reported in the format and level of detail required by the appropriate guidelines and example DERs.

The following types of studies will be provided by BPPD/OPP for analyses and evaluations:

Requirement	MPB Guideline(s)	BPB Guideline(s)
Product chemistry and identity	885.1100 to 885.1500	880.1100 to 880.1400
Physical and Chemical Properties	830.6302 to 830.7300	830.6302 to 830.7950
Manufacturing process	885.1200	830.1700 to 830.1800
Residue chemistry	885.2100 to 885.2600	860.1100 to 860.1650

Acute toxicity/pathogenicity	885.3050 to 885.3550 870.1100 to 870.2500	870.1100 to 870.5375
Developmental toxicity	N/A	870.3700
Neurotoxicity	N/A	N/A
Genotoxicity	N/A	870.5300 & 870.5895
Subacute toxicity	885.3600	870.3100 to 870.3465
Reproductive toxicity	885.3650	870.3700
Chronic toxicity	870.4200, 870.7800, 885.3000	880.3800 to 870.5380
Oncogenicity	N/A	N/A
Efficacy	810 series (or non-guideline)	810 series (or non-guideline)
Ecotoxicity (non-targets)	Tier 1: 885.4050 to 885.4380 Tier 2-3: 885.5200 to 885.4750 Tier 4: 850.1950 to 850.4300	Tier 1: 850.1010 to 880.4350 Tier 2: 850.4225 & 850.4250 Tier 3: 850.1300 to 850.4450
Environmental fate	Non-guideline	835.1230 to 835.440; 880.4425
Gene Flow	Non-guideline	N/A
Synergism	Non-guideline	Non-guideline
Resistance Management	Non-guideline	N/A
Companion Animal Study	N/A	870.7200

VI. COMMUNICATION AND TECHNICAL DIRECTION

The EPA's Office of Pesticide Programs/Biopesticide and Pollution Prevention Division (BPPD) will ship via UPS the data review requests to the contractor, on a bi-weekly basis. Each data review is tracked by a unique tracking number called a MRID number.

Technical direction will be given from time to time by telephone, by email, or other written means. Any verbal issuance of TD will be confirmed in writing within 5 calendar days.

At any time, the Contractor shall notify the Agency (Contracting Officer, Project Officer and/or WAM) of any concerns and/or issues related to data review, so that they may be remedied immediately.

VII. DELIVERABLES

As per the Contract, the Contractor shall provide the Agency with a work plan within 14 days of receipt of the Work Assignment. The Project Officer (PO) will review the work plan and provide the Contractor with any changes/suggestions or revisions, in writing. Work plan approval/disapproval, and revision (if necessary), and the timelines involved, will proceed as stipulated in the Contract. The work plan should address (among other subjects as needed) the technical approach, resources, timeline, and due dates for all deliverables.

For most deliverables, the EPA WAM will assign a tentative due date to the task when its package and instruction is routed to the Contractor. If, within three business days of such routing, the Contractor expresses no concern regarding the due date, the date shall be deemed settled by tacit agreement. If the date remains unsettled after three days, a new date not exceeding normal time frames will be assigned by mutual agreement.

The contractor shall prepare written reports of efficacy studies and/or protocol reports to include any other supporting documentation related to the evaluations conducted under this task area. All work performed shall conform to EPA standards for QA/QC, DER formatting, and protocols submitted to and approved by OPP. All deliverables under this WA shall be submitted via UPS (next day delivery) to the cognizant EPA WAM for review and approval along with the original paper copies of the registrant data. Deliverables shall be presented as electronic files: MS Word (2007) format on CD/DVD. Inside each deliverable package that is shipped a custody receipt shall be placed inside stating the data belongs to BPPD, the WAM's name and phone number, and actual hours and costs per MRID number.

The Contractor shall provide each monthly technical and financial progress report as per the Contract. The report shall be submitted on or before the 15th of each month (following the completion of the first reporting period), with a copy provided (preferably by email) to the EPA Project Officer and WAM. Among other data required, the report shall list each review action completed (finished and delivered) during the reporting period, along with its data package bar code, number of studies, technical labor hours, and staff levels. Of course, these stipulations will not reduce any of the contractual monthly reporting obligations.

Content and format of the monthly technical and financial progress report must be intelligible and must be sufficient to support the Agency's review of invoicing, budget status, and technical progress. To this end, any new reporting needs found may be requested by technical direction to the degree permissible under the Contract.

SCHEDULE OF DELIVERABLES:

Deliverable	Schedule	Format/Distribution
Acknowledgement of Work Assignment (WA)	5 calendar days after WA is issued by Contracting Officer (CO)	Email acknowledgement to CS, PO, and WAM

Work Plan (WP)	14 calendar days after WA is issued by CO	Email a copy to CS, PO, and WAM
Quality Assurance Plan	Same as for the WP	Included with WP
Monthly Progress Report	15th of each month (following completion of 1st reporting period)	Email a copy to CS, PO and WAM
Monthly Invoices	15th of each month (following completion of 1st reporting period)	Email a copy to CS, and PO
Data review action	Due date assigned by WAM when packaged is routed. 3 business days for any concerns and renegotiation regarding due date	MS Word (2007) format, on CD/DVD per action, returned to WAM
Other	As per Contract	As per Contract

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 4 04

☒ Original ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment
EP-W-11-014	02/1/2015 to 01/31/2016 ☐ Base ☒ Option Period Number: IV	Consolidate, Review & Evaluation of Scientific Data on Pesticides for HED, Task #4 of PWS

Contractor: SUMMITEC CORPORATION

Specify Section and Paragraph of Contract SOW:

Purpose:
☒ Work Assignment Initiation ☐ Work Assignment Close-Out
☐ Work Assignment Amendment ☐ Incremental Funding
☐ Work Assignment Approval

Periods of Performance: From Date of CO Signature To 01/31/2016

Comments: The estimated level of effort for this work assignment is 3,960 hours.

☐ Superfund

Accounting and Appropriations Data

☐ Non-Superfund

Line	DC (Max 6)	Budget/FYs (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

	Cost/Fee	LOE
Contract Period: 02/01/2015 To 01/31/2016		
Previously Approved		
This Action		
Total		

Work Plan / Cost Estimate Approvals

Contractor WP Dated:	Cost/Fee:	LOE:
Cumulative Approved:	Cost/Fee:	LOE:

Work Assignment Manager Name
Lori Brunsman
(Signature) (Date)
Branch/Mail Code: 7509P
Phone Number: (703) 308-2902
Fax Number:

Project Officer Name
LaTangila Edwards
(Signature) (Date)
Branch/Mail Code: 7509P
Phone Number: (703) 305-7170
Fax Number:

Other Agency Official Name
(Signature) (Date)
Branch/Mail Code:
Phone Number:
Fax Number:

Contracting Officer Name
Christine Edwards
(Signature) 3/3/2015 (Date)
Branch/Mail Code: 3803R
Phone Number: (202) 564-2182
Fax Number:

Contractor Acknowledgement of Receipt and Approval of Workplan *(Signature and Title)*

Date

EPA Form 1900-69 (Rev. 07-95)

WORK ASSIGNMENT-HED TOX SUPPORT
Statement of Work

I. TITLE

WA 4-04, Consolidate, Review & Evaluation of Scientific Data on Pesticides for HED, Task #4, of PWS

The contractor has furnished facilities, materials, and the necessary professional, technical, and supporting personnel for performance of the work required by this Work Assignment, described in the Statement of Work in accordance with the Terms and Conditions of the contract, and specifically described in Task 4.

II. WORK ASSIGNMENT MANAGER (WAM)/CONTRACTING OFFICER REPRESENTATIVE (COR) WORK ASSIGNMENT LEVEL

Lori Brunsman
2777 South Crystal Drive
Rm S-10934
Arlington, VA 22202
Phone: (703) 308-2902

III. PERIOD OF PERFORMANCE

Date of issuance through January 31, 2016

IV. LEVEL OF EFFORT (LOE)

The estimated LOE for this WA is 3,961 hours

V. BACKGROUND

The Environmental Protection Agency (EPA) and the states (usually the State Department of Agriculture) register or license pesticides for use in the United States. In addition, anyone planning to import pesticides for use in the U.S. must notify EPA. EPA receives its authority to register pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under the mandates of FIFRA and the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, and as modified by the Pesticide Registration Improvement Act (PRIA), a pesticide may be registered if its use will not result in unreasonable risks or unreasonable adverse effects to humans or the environment. EPA's Office of Pesticide Programs (OPP) has instituted procedures for the registration and ongoing reregistration of pesticides. Data submitted by pesticide manufacturers (registrants), other EPA programs, other Federal agencies, the states, Indian tribes, cities, municipalities, private citizens, data published in the public and open literature are used to determine whether pesticides and their proposed uses

may pose unreasonable adverse effects on human health and the environment. OPP evaluates the data and determines whether the data are adequate for regulatory decision-making or whether additional data are required from the registrants, performs hazard and risk assessments on the data to decide whether the pesticide or its proposed uses should be registered in compliance with FIFRA; and determines whether new procedure or methodologies for estimating possible pesticide hazards to human must be developed. After the enactment of the Food Quality Protection Act of 1996, EPA has initiated implementation efforts through the Safety Advisory Committee (FSAC). In addition to modification of minor use provisions and the setting of tolerances in processed commodities, the Act has required increased monitoring of pesticide residues in food and water, as well as the complete re-evaluation of all registered pesticides on a 15-year cycle. Furthermore, the Act requires the Agency to more closely regulate pesticides in terms of exposure to infants and children through diet. Exposure from multiple sources (i.e., food, water, and residential) is to be aggregated into a comprehensive risk assessment. In addition, EPA's assessment must incorporate risk due to other chemicals with a similar mode of action/mechanism of toxicity.

Technical direction will define all requirements, including studies and data packages for review; toxicity endpoints to assess; pertinent science issues, questions, or gaps to be addressed in the assessments; identify OPP expert reviewers who will review and evaluate the contractor's reports, level-of-effort hours to be expended in the reviews, schedules, and any other background, related information and/or specifications required for the contractor to complete the assignment in a fully satisfactory manner. An understanding of the EPA Guidelines: Office of Chemical Safety Pollution Prevention (OCSPP) Harmonized Test Guidelines, Series 870- Health Effects Test Guidelines; Data Requirements for Pesticides (40 CFR Part 158); Health Effects Division: Standard Evaluation Procedures (SEPs) for health endpoints available from National Technical Information Service (NTIS), EPA Risk Assessment Guidelines (51 FR 33992-34054), and Good Laboratory Practices (GLPs) (40 CFR Part 160) for toxicological data development is required for this work assignment.

Some studies may be submitted electronically. Consequently, transportation of studies for review must be provided by the contractor that is timely, most cost-effective, and FIFRA Confidential Business Information (CBI) secure. In addition the contractor shall provide CBI secure storage for those studies while they are in its custody. An acceptable security plan must be prepared to safeguard these studies. To perform under this contract, the contractor will need to have access to FIFRA CBI data submitted by pesticide registrants to EPA. Disclosure of FIFRA CBI data to contractors is provided for under Section 10 (c) of the FIFRA and 40 CFR 2.307. Consequently, the contractor must be cleared for access to FIFRA CBI and must control FIFRA CBI data according to the requirements specified for contractors in the EPA publication, FIFRA Information Security Manual, dated July 1988.

VI. SCOPE OF WORK

The purpose of this work assignment is to provide technical expertise for the review and evaluation of toxicology data to assist EPA in meeting its legislative mandates. To support EPA's

OPP HED, the contractor shall review and evaluate toxicological and pharmacological studies reporting tests of pesticides in laboratory animals, clinical reports, monitoring and epidemiological studies, and accidental pesticide exposure incident studies. The studies are conducted in accordance with OCSPP Harmonized Test Guidelines and may include data on the following biological/biochemical and health effect parameters of concern from studies including: metabolism; pharmacokinetics; carcinogenicity; mutagenicity; reproduction; developmental; neurotoxicity; acute, subchronic and chronic studies via the oral, dermal and/or inhalation routes. Pathology, endocrinology, immunotoxicity, cholinesterase inhibition, epidemiology, and other special studies may be included for data evaluations. The contractor shall conduct expert reviews of complex science issues and perform data extraction/entry from toxicological data summaries, using computerized data bases.

Project 1 - Review and Evaluation of Health-Related Pesticide Toxicity Data

Each toxicology study for a pesticide will be evaluated and reported as specified by the requirements of HED's Data Evaluation Reports (DERs). A sample of the DER format for 90-Day Oral Toxicity (rodent study) is attached. This format shall be followed in the preparation of DERs. For each assigned study, the contractor shall complete a DER by performing an in-depth examination of the materials and methods employed; an in-depth examination of the reported results; an in-depth scientific assessment of the study; a description of conclusions that summarize the overall significance of the study; and a concise summary of the study and the results, discussing as appropriate at dose levels, no observable adverse effects levels (NOAEL), lowest observable adverse effects levels (LOAEL) and significant toxicological effects. The contractor shall also identify whether the studies were performed in accordance with accepted methodologies or guidelines as prescribed in EPA's published guidelines and whether the data reported in the studies are reliable for characterizing health hazards and risks to humans.

The review and evaluation of each study will include review and analysis of all necessary graphic displays of data, summary tables, and references needed to substantiate technical details supporting the reviewer's conclusions. All DERs shall be signed and dated both by the contractor's primary and secondary science reviewers and the quality assurance reviewer.

Project 2- OCSPP Harmonized Test Guideline Support

If OPP's review of its current Pesticide Assessment guidelines indicates a need for updates or other revision, upon receipt of technical direction, the contractor shall conduct a state-of-science review of the literature characterizing test methodologies and science issues related to toxicity endpoints, analyze issues vis-a-vis the current testing methodologies and guidelines, prepare recommendation reports regarding modification of current testing methodologies and guidelines, and prepare a draft revised or new guideline for review by OPP experts. Revisions shall address the categories of data required, the methods by which that data should be obtained, methods for evaluating such data, submission of protocols, international harmonization (e.g., OECD, NAFTA), and development of exposure assessment criteria. In reviewing these guideline documents, the contractor's efforts shall identify and evaluate other EPA guidance on exposure

assessment and exposure parameter values. The contractor shall also provide technical support to EPA in developing testing requirements for CFR 40, Part 158, if requested. If requested, the contractor shall (1) submit the proposed revisions of Series 870 Guidelines to peer reviewers approved by the EPA COR; (2) submit a synopsis of the peer review comments; and (3) provide technical recommendations thereon.

Project 3 - Pathology Evaluations

EPA shall submit data to the contractor for pathology evaluation. If submitted data require an expert pathology review for assessment of carcinogenicity in the DERs, upon receipt of a technical direction, the contractor shall perform in-depth reviews of data and slides from tumors and other lesions, gross and histological changes (including evaluations of slides produced for specific chemicals) and provide definitive, expert reports of the pathology findings for review by the OPP scientists. The pathologist must have knowledge and experience in the evaluation of the toxicity and carcinogenicity studies in laboratory animals. The pathologist shall review and interpret data for neoplastic and non-neoplastic lesions in target organs; interpret the significance of gross and microscopic pathology in animals in relationship to the species, strains, and sexes tested; evaluate dose-response and carcinogenic response; discuss the relevance of the carcinogenic responses seen in animals to humans; provide context for the time-to-tumor occurrence and/or time to death, analyze the increase in the proportion of the tumors that are malignant; interpret clinical signs, clinical chemistry, hematology and other data in relationship to toxic and/or carcinogenic responses; have knowledge of the historical control data for the animal species, strains, and sexes that could be used along with the concurrent control data in the evaluation of carcinogenic response, and participate in workgroups which classify pesticide chemicals in accordance with the EPA Risk Assessment Guidelines for Classifying Carcinogens.

Project 4 - Special Projects: Evaluations of Complex Toxicological Data and Issues

In addition to those studies identified in projects 1 through 3 above, health effects data submitted to OPP for evaluation may involve unusually difficult and complex issues that require expert analyses. Upon receipt of technical direction, the contractor shall perform expert analyses of difficult and complex toxicological issues. The technical direction will provide key scientific questions and data sets as appropriate that the contractor shall analyze and answer. These analyses shall assess the overall significance of the findings as they relate to the expected human health effects. Such studies may focus on endocrinology (including endocrine disruption), epidemiology, immunology, cholinesterase inhibition, synergistic interaction, behavioral pharmacology, biostatistics, mode of action studies, and risk assessment. To conduct these complex analyses, the contractor shall identify expert scientists in the required scientific disciplines, convene work groups or meetings to conduct coordinated reviews, conduct the workgroup or meetings, and prepare draft reports.

Project 5 - Preparation of Chemical Toxicity Data Summary Abstracts

For toxicity databases, particularly the Toxicological Reference Database and Integrated

Hazard Assessment Data Base (IHAD), upon receipt of a technical direction, the contractor shall extract from DERs, Peer Reviews, Reference Dose (RfD) decisions, and special review data that characterize the toxicity of pesticides that the Contracting Officer's Representative (COR) makes available. The contractor shall also enter abstracted data into computerized database management programs. The contractor shall conduct quality assurance measures for both data extraction and entry.

Project 6 - Conduct Backup Literature Search and Hard Copy Acquisition

Occasionally during performance of Project 1 through 3, the data furnished by OPP will have gaps that will have to be filled from the open literature or private literature sources. When the OPP identifies these gaps or when the contractor identifies gaps to the OPP and the OPP concurs that the gap is significant, upon receipt of a technical direction that requires literature search or acquisition, the contractor shall conduct literature searches on National Library of Medicine, Toxline, and other standard toxicology databases and acquire the literature for review in the assessment of health effects for pesticides. The contractor shall provide to the COR either by paper copy or electronic media (CD/DVD/electronic transfer) the listing of literature that results from the literature search, and paper copy of the literature acquired with the first draft of the report.

The following are a few of the types of studies will be provided by OPP/HED for analysis and evaluation.

Guideline No.	Task Description
870.7800	(10) Immunoxicity Studies for Review
870.3100	(10) Sub chronic
870.3700	(5) Dev Neurotoxicity Studies
870.6200a	(46) Acute
870.3465	(2) Inhalation
870.3150	(3) 90 day oral
870.3800	(3) 2-generation repro
870.3200	(4) 21 day dermal
	(2) Acute neurotoxicity range finding
870.7485	(3) Metabolism

Task 6-121- Silver Acetate Registration 49514101; Animal Audit and Stats on Repro Study
6-122 Spinetoram Registration 47143801: Mouse Onco
6-123 Hymexazol Registration 42960018, 42960019, 42960022, 42826309; Chronic Rat, Mouse Onco, Rabbit Teratogenesis, 2-Gen Rat
6-124 Cloransulam-methyl Registration 49078202: Subchronic Neurotox
6-125 Dichlobenil Registration 49542901; 28-Day Olfactory Rat Tox Study
6-126 Phosmet Registration 49529001; Comparative Cholinesterase
6-127 Metalaxyl-M Registration 48865901 48865902, 48865903; Acute Neurotox, Subchronic Neurotox, Immunotoxicity
6-128 Dichlobenil Registration 49547401; 28-Day Olfactory at Tox Study6-59

VII. COMMENTS AND TECHNICAL DIRECTION

HED will ship the data review requests to the contractor via UPS, email, place documents on the contractor's portal or use other electronic technology when made available. Each data review is tracked by a unique tracking number.

The Project Officer (contract-level COR) is the primary representative of the contracting officer authorized to provide technical direction; in addition, this work assignment's respective WAM/COR may provide technical direction to the contractor. Technical direction will be given from time to time by telephone, by email, or other written means. Any verbal issuance of technical direction will be confirmed in writing within 5 calendar days. At any time, the contractor shall notify the contracting officer or CORs of any concerns and/or issues related to data review, so that they may be remedied immediately.

A detailed work plan and cost estimate of the attached chart of the types of studies for review is required for the work assignment. The contractor shall provide a work plan for each task upon receipt. The contractor shall provide a weekly report (the Time/Action Plan) to the COR which

identifies project staff and all activities and milestones associated with the task assignments planned and in progress. The information on the weekly Time/Action Plan on planned and in progress tasks shall be combined to create the monthly reports which will be referenced when the Voucher Validation review is performed monthly at the end of each billing cycle.

VIII. DELIVERABLES

The contractor shall submit a work plan within 14 days of receipt of the Work Assignment. Work plan approval/disapproval, and revision (if necessary), and the timelines involved, will proceed as stipulated in the contract. The work plan should address (among other subjects as needed) the technical approach, resources, timeline, and due dates for all deliverables.

For most deliverables, the EPA WAM/COR will assign a tentative due date to the task when its package and instruction is routed to the contractor. If within three business days, the contractor expresses no concern regarding the due date; the date shall be deemed settled by tacit agreement. The contractor shall prepare written reports that conform to EPA standards for QA/QC, DER formatting, and protocols submitted to and approved by OPP. All deliverables under this WA shall be submitted via email/UPS or by a specified electronic method. Each deliverable package should be returned with the task assignment form completed with the actual hours used to complete the task, a custody sheet stating the data belongs to HED and the WAM's name and phone number.

The contractor shall provide a monthly technical and financial progress report as per the contract. The report shall be submitted on or before the 15th of each month (following the completion of the first reporting period), with a copy provided (preferably by email) to the Project Officer and WAM. Among other data required, the report shall list each review action completed (finished and delivered) during the reporting period, along with its data package bar code, number of studies, technical labor hours, and staff levels. These stipulations will not reduce any of the contractual monthly reporting obligations. Content and format of the monthly technical and financial progress report must be intelligible and must be sufficient to support the Agency's review of invoicing, budget status, and technical progress. To this end, any new reporting needs found may be requested by technical direction to the degree permissible under the contract.

SPECIFIC SCHEDULE OF DELIVERABLES:

Deliverable	Schedule	Format/Distribution
Acknowledgement of Work Assignment (WA)	5 calendar days after WA is issued by Contracting Officer (CO)	Email acknowledgement to CO and CORs (formally called PO and WAM)
Work Plan (WP)	Within 14 calendar days after WA is issued by CO	Email a copy to CO, CORs
Quality Assurance Plan	Within 14 calendar days after WA is issued by CO	Include a copy in the WP

Monthly Progress Report	15th of each month (following completion of 1st reporting period)	Email a copy to CO and CORs
Monthly Invoices	15th of each month (following completion of 1st reporting period)	Email a copy to CO and CORs
Data review action	Provided through technical direction in current EPA MS Word version, via email, etc., Contract has three business days for any concerns, and renegotiation regarding due date	MS Word (2007) format, by on CD/DVD or via email per action to the WAM/COR
Other	As per contract	As per contract

EPA Reviewer: _____ **Signature:** _____
[Insert Branch], Health Effects Division (7509P) **Date:** _____
EPA Secondary Reviewer: _____ **Signature:** _____
[Insert Branch], Health Effects Division (7509P) **Date:** _____

Template version 09/11

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: 90-Day Oral Toxicity *[feeding, gavage or water]-[species]*; OPPTS 870.3100 [§82-1a] (rodent); OECD 408.

PC CODE: **DP BARCODE:** D

TEST MATERIAL (PURITY): *[use name of material tested as referred to in the study (common agency chemical name in parenthesis)]*

SYNONYMS: *[other names and code names]*

CITATION: Author *[up to 3, see SOP for exact format]* (Date) Title. Laboratory name (location if needed). Laboratory report number, full study date. MRID *[no hyphen]*. Unpublished *(OR if published, list Journal name, vol.: pages)*

SPONSOR: *(Name of Study Sponsor - indicate if different from Applicant).*

EXECUTIVE SUMMARY:

In a 90-day oral toxicity study (MRID *[number])* *[Chemical name (% a.i., batch/lot #)]* was administered to *[(# of animals) species, strain]*/sex/dose in *[diet, water, by gavage]* at dose levels of 0, x, x, or x ppm (equivalent to 0, x, x, x mg/kg bw/day).

[Describe toxicity briefly following instructions for exec summary paragraph 2. If there is no toxicity, state that there were no compound related effects on mortality, clinical signs, body weight, food consumption, hematology, clinical chemistry, organ weights, or gross and histologic pathology. Note if there was a NOAEL for clinical findings and when they occurred (for Acute reference dose consideration during subsequent risk assessment.)]. **The LOAEL is mg/kg/day, based on . The NOAEL is mg/kg/day.**

This 90-day oral toxicity study in the *(rodent species)* is *[acceptable, unacceptable (guideline, non-guideline); note if it is a range-finding study]* and satisfies *(does not satisfy)* the guideline

requirement for a 90-day oral toxicity study (OPPTS 870.3100; OECD 408) in */rodent species/. [If unacceptable, why and is it upgradable. If it does not satisfy the requirement, concisely list only major deficiencies or refer to deficiency section.]*

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were *(not)* provided. *[Discuss deviations from regulatory requirements.]*

I. MATERIALS AND METHODS:

A. MATERIALS:

1. Test material: */as named in study/*

Description:	(e.g. technical, nature, color, stability)
Lot/batch #:	
Purity:	% a.i.
Compound stability:	
CAS # of TGAI:	*Number or Not available*
Structure:	*[Structure] Jpeg format or Not available*

2. Vehicle and/or positive control: */when appropriate/*, Lot/Batch # ; Purity

3. Test animals:

Species:		
Strain:		
Age/weight at study initiation:		
Source:		
Housing:		
Diet:	*(describe)*	*ad libitum*
Water:	*(describe)*	*ad libitum*
Environmental conditions:	**Temperature:**	°C
	Humidity:	/hr
	Air changes:	hrs dark/ hrs light
	Photoperiod:	
Acclimation period:		

B. STUDY DESIGN:

1. In life dates: Start: ; End:

2. Animal assignment: Animals were assigned */note how assigned, eg., random/* to the test groups noted in Table 1. ***[The information in this table is MANDATORY]***

TABLE 1: Study design *[change heading and units as appropriate for method of administration]*

Test group	Conc. in diet *(units)*	Dose to animal *(units)*	# Male	# Female
Control				
Low				
Mid				
High				

3. **Dose selection rationale:** The dose levels were selected based on the results from [state study type(s)] where [route] - administration of up to [dose] resulted in [state effects]. *[Use data from range-finding study if available. Put more detail when available in a 1-2 page appendix at the end of the review]*

4. **Diet preparation and analysis:** Diet was prepared *[how often]* by mixing appropriate amounts of test substance with *[type of food eg. Purina Certified Rodent Diet #5001]* and was stored at *(#°C)* temperature. Homogeneity and stability were tested at *[how often]*. During the study, samples of treated food were analyzed *[when and at what dose levels]* for stability and concentration.

Results:

Homogeneity analysis: *[range]*

Stability analysis: *[range of values]*

Concentration analysis: *[range of values (The analytical data indicated that the mixing procedure was adequate and that the variance between nominal and actual dosage to the animals was acceptable.)]*

5. **Statistics:** *[list parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. If inappropriate, provide alternative/rationale]*

C. METHODS:

1. Observations:

1a. Cageside observations: Animals were inspected *[frequency]* for signs of toxicity and mortality.

1b. Clinical examinations: Clinical examinations were conducted [*frequency*].

1c. Neurological evaluations: The following evaluations (measurements) were performed

on day [*insert treatment day*]: *[list parameters measured]* [*If neurological evaluations were omitted, give explanation for why, such as available from other studies*]

2. **Body weight:** Animals were weighed *[frequency]*.

3. **Food consumption and compound intake:** *[if feeding study]:* Food consumption for each animal was determined and mean daily diet consumption was calculated as g food/kg body weight/day. Food efficiency [if given] *(body weight gain in kg/food consumption in kg per unit time X 100)* and compound intake (mg/kg bw/day) values were calculated as time-weighted averages from the consumption and body weight gain data.

4. **Ophthalmoscopic examination:** Eyes were examined *[when - before test and at termination?, which dose groups - control and high dose or all groups?]*

5. **Hematology and clinical chemistry:** Blood was collected *[were animals fasted? time of collection and how many animals]* for hematology and clinical chemistry from all surviving animals. The CHECKED (X) parameters were examined.

   a. **Hematology:**

	Hematocrit (HCT)*		Leukocyte differential count*
	Hemoglobin (HGB)*		Mean corpuscular HGB (MCH)*
	Leukocyte count (WBC)*		Mean corpusc. HGB conc.(MCHC)*
	Erythrocyte count (RBC)*		Mean corpusc. volume (MCV)*
	Platelet count*		Reticulocyte count
	Blood clotting measurements*		
	(Thromboplastin time)		
	(Clotting time)		
	(Prothrombin time)		

* Recommended for 90-day oral rodent studies based on Guideline 870.3100

b. Clinical chemistry:

X	ELECTROLYTES	X	OTHER
	Calcium		Albumin*
	Chloride		Creatinine*
	Magnesium		Urea nitrogen*
	Phosphorus		Total Cholesterol*
	Potassium*		Globulins
	Sodium*		Glucose*
	ENZYMES (more than 2 hepatic enzymes eg., *)		Total bilirubin
	Alkaline phosphatase (ALK)*		Total protein (TP)*
	Cholinesterase (ChE)		Triglycerides
	Creatine phosphokinase		Serum protein electrophoresis
	Lactic acid dehydrogenase (LDH)		
	Alanine aminotransferase (ALT/also SGPT)*		
	Aspartate aminotransferase (AST/also SGOT)*		
	Sorbitol dehydrogenase*		
	Gamma glutamyl transferase (GGT)*		
	Glutamate dehydrogenase		

* Recommended for 90-day oral rodent studies based on Guideline 870.3100

6. **Urinalysis***: Urine was collected from *(fasted?)* animals at *[times]*. The CHECKED (X) parameters were examined.

	Appearance*		Glucose
	Volume*		Ketones
	Specific gravity/osmolality*		Bilirubin
	pH*		Blood/blood cells*
	Sediment (microscopic)		Nitrate
	Protein*		Urobilinogen

* Optional for 90-day oral rodent studies

7. **Sacrifice and pathology**: All animals that died and those sacrificed on schedule were subjected to gross pathological examination and the CHECKED (X) tissues were collected for histological examination [*note if not all collected tissues were examined*]. The (XX) organs, in addition, were weighed.

X	DIGESTIVE SYSTEM
	Tongue
	Salivary glands*
	Esophagus*
	Stomach*
	Duodenum*
	Jejunum*
	Ileum*
	Cecum*
	Colon*
	Rectum*
	Liver*–
	Gall bladder (not rat)*
	Bile duct (rat)
	Pancreas*
X	**RESPIRATORY**
	Trachea*
	Lung*
	Nose*
	Pharynx*
	Larynx*

X	CARDIOVASC./HEMAT.
	Aorta*
	Heart*+
	Bone marrow*
	Lymph nodes*
	Spleen*+
	Thymus*+
X	**UROGENITAL**
	Kidneys*+
	Urinary bladder*
	Testes*+
	Epididymides*–
	Prostate*
	Seminal vesicles*
	Ovaries*+
	Uterus*+
	Mammary gland*

X	NEUROLOGIC
	Brain*+
	Peripheral nerve*
	Spinal cord (3 levels)*
	Pituitary*
	Eyes (optic nerve)*
X	**GLANDULAR**
	Adrenal gland*+
	Lacrimal gland
	Parathyroid*
	Thyroid*
X	**OTHER**
	Bone (sternum and/or femur)
	Skeletal muscle
	Skin*
	All gross lesions and masses*

* Recommended for 90-day oral rodent studies based on Guideline 870.3100
\+ Organ weights required for rodent studies.

II. RESULTS:

[describe findings, include tables if needed; tables are recommended to depict any treatment-related findings, thus limiting use of text to highlight specific points]:

A. OBSERVATIONS:

1. Clinical signs of toxicity: *[include cageside observations and clinical examinations; note when signs were first observed]*

2. Mortality:

3. Neurological evaluations:

B. BODY WEIGHT AND WEIGHT GAIN:

[required: include a table of body weight gain, especially 0-30, 30-60, 60-90 days]

TABLE 2. Average body weights and body weight gains during 90 days of treatment [a]

Dose rate *[insert units]*	Body weights (g±SD)				Total weight gain	
	Week -1	Week 1	Week 7	Week 13	g	% of control
Male						
0						
Low						
Mid						
High						
Female						
0						
Low						
Mid						
High						

[a] Data obtained from pages *(insert page #s)* in the study report.
* Statistically different ($p < 0.05$) from the control.
** Statistically different ($p < 0.01$) from the control.

C. FOOD CONSUMPTION AND COMPOUND INTAKE:

[if feeding study]

1. Food consumption:

Subchronic (90-day) Oral Toxicity Study (rodents) (year / study) / Page 7 of 19
NAME OF TECHNICAL HC Code_____ OPPTS 870.3100/ OACO 4.3.1/ OECD 408

2. Compound consumption: (time-weighted average) - *[include compound intake in table 1]*

3. Food efficiency: (if relevant) - *[relate to any changes in body weight]*

D. OPHTHALMOSCOPIC EXAMINATION:

E. BLOOD ANALYSES:

[Tables to show treatment-related findings are OPTIONAL, but recommended for treatment-related findings]:

1. Hematology: *[relate to any histological findings]*

2. **Clinical chemistry:** *[relate to any histological findings]*

F. URINALYSIS:

G. SACRIFICE AND PATHOLOGY:

[Tables are OPTIONAL but recommended for treatment-related findings; limit text to integration of findings, highlights]

1. **Organ weight:** *[absolute and relative as appropriate, relate to any histological changes]*

2. **Gross pathology:**

3. **Microscopic pathology:** *[relate with other findings, as appropriate]*

III. DISCUSSION AND CONCLUSIONS:

A. INVESTIGATORS' CONCLUSIONS:

B. REVIEWER COMMENTS:

[Discuss any discrepancy with investigators' conclusions; state LOAEL and basis for setting the LOAEL; state NOAEL. Note if there was a LOAEL/NOAEL for clinical findings and when they occurred (for Acute reference dose consideration during subsequent risk assessment).]

C. STUDY DEFICIENCIES:

[List each deficiency (distinguishing between major and minor ones) with the data required to resolve the deficiency. If no data can be provided to satisfy the deficiency, indicate impact on the regulatory decision.]

Attachment 2 –Example Work Plan for each Task

Company Name Work Plan: Task 1-4-A-01

Company Name received Task Assignment X-YY-ZZ from the EPA Project Officer (**name of PO**) on date received, requesting that **Company Name** evaluate and prepare DERs for task **description**. The studies are shown in the **SAMPLE** table below.

This assignment is covered under Task A of the Performance Work Statement for EPA Contract No. **EPW00STUV**. Each unpublished study was assigned a LOE of **X** or **Y** hours by EPA, for a total of **TOTAL** hours. The proposed due date for this assignment is date due.

SAMPLE table:

#	Chemical (PC code)	MRID #	Study Type	Estimated LOE
1	Chemical Name (PC Code)	XXXXXXXX	Pubertal Rat Assay -Female (890.1450)	90
2		XXXXXXXX	Pubertal Rat Assay -Male (890.1500)	90
3		XXXXXXXX	14-day oral Range-finding study	5
			Total Hours:	**185**

Company Name is currently tracking the expenditure of hours used in each stage of the review process for each type of study in order to develop an accurate assessment of the time required to review each type of **describe study**.

Company Name will evaluate, summarize, and prepare DERs for the above **describe study**, and submit Microsoft WORD file copies of the DERs to the EPA PO. **Company Name** will deliver the DERs by date due. Based on the level of expertise required for this assignment and the estimated LOE, the T&M costs for TA X-YY-ZZ should not exceed $ **cost estimate**.

Signed by
Company Name Program Manager

Distribution of Work by GSA Labor Category for TA X-YY-ZZ.			
GSA Labor Category	**Hourly Rate**	**Projected hours**	**Projected Cost**
Program Manager			
Senior Scientist			
Staff Scientist			
Jr. Scientist			
Jr. Env. Support Scientist			
	Totals:		**$ cost estimate**

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 4-06

☒ Original ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment
EP-W-11-014	02/1/2015 to 01/31/2016 ☐ Base ☒ Option Period Number: TV	AD/PSB

Contractor: SUMMITEC CORPORATION

Specify Section and Paragraph of Contract SOW:

Purpose:
☒ Work Assignment Initiation ☐ Work Assignment Close-Out
☐ Work Assignment Amendment ☐ Incremental Funding
☐ Work Assignment Approval

Periods of Performance: From: Date of CO Signature To: 01/31/2016

Comments:
The estimated level of effort for this work assignment is 287 hours.

☐ Superfund

Accounting and Appropriations Data

☐ Non-Superfund

Line	DC (Max 5)	Budget/FYs (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 02/01/2015 To 01/31/2016	Cost/Fee	LOE
Previously Approved		
This Action		
Total		

Work Plan / Cost Estimate Approvals

Contractor WP Dated: Cost/Fee: LOE:

Cumulative Approved: Cost/Fee: LOE:

Work Assignment Manager Name: Nathan Mottl (Signature) (Date)	Branch/Mail Code: 7510P Phone Number: (703) 305-0208 Fax Number:
Project Officer Name: LaTangila Edwards (Signature) (Date)	Branch/Mail Code: 7509P Phone Number: (703) 305-7170 Fax Number:
Other Agency Official Name (Signature) (Date)	Branch/Mail Code: Phone Number: Fax Number:
Contracting Officer Name: Christine Edwards (Signature) 2/26/2015 (Date)	Branch/Mail Code: 3803R Phone Number: (202) 564-2182 Fax Number:

Contractor Acknowledgement of Receipt and Approval of Workplan *(Signature and Title)* | Date

EPA Form 1900-69 (Rev. 07-95)

WORK ASSIGNMENT HUMAN EXPOSURE STATISTICAL ANALYSIS TO SUPPORT THE HUMAN STUDIES REVIEW BOARD (HSRB) REVIEW STATEMENT OF WORK

I: TITLE

WA 4-06 Technical Support to Statistically Review and Evaluate Human Exposure Studies for the Human Studies Review Board (HSRB)

II: WORK ASSIGNMENT MANAGER

Nathan Mottl
Risk Assessment and Science Support Branch, AD, OPP
U.S. Environmental Protection Agency
Ariel Rios Building (7510P)
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
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III: LEVEL OF EFFORT

Labor Hours: 287 hours

Duration: Date of issuance thru January 31, 2016

IV: BACKGROUND

Pesticides are chemicals that are deliberately introduced into the Environment for a specific purpose. As specified by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) and as modified by the Pesticide Registration Improvement Act (PRIA), a pesticide may be registered if its use will not result in unreasonable risks or

unreasonable adverse effects to human health or the environment. The risks in this case are a combination of the inherent toxicity of the pesticide and the extent to which people are exposed to it. The goal of exposure assessments is to present an accurate and realistic picture of human contact with the pesticide on which to base the risk assessment. Companies registering or reregistering pesticides (registrants) submit studies to the Environmental Protection Agency (EPA) that characterize and quantify human exposures resulting from prescribed use of a given pesticide formulation. These pesticide exposure studies, which may focus on either occupational (e.g., mixer/loader/applicator or post-application/reentry) or on residential exposures, are used by EPA for calculation of total body exposure for a given pesticide-use scenario.

The Human Studies Review Board (HSRB or Board) is a Federal advisory committee operating in accordance with the Federal Advisory Committee Act (FACA) 5 U.S.C. App.2 § 9. The HSRB provides advice, information, and recommendations on issues related to scientific and ethical aspects of human subjects research. The major objectives are to provide advice and recommendations on: a. research proposals and protocols; b. reports of completed research with human subjects; and c. how to strengthen EPA's programs for protection of human subjects of research. The HSRB reports to the EPA Administrator through EPA's Science Advisor.

Before relying on the human studies data for exposures, EPA must evaluate exposure studies submitted by registrant task forces to determine their adequacy according to HSRB procedures, submit the study for review through the HSRB, and address any questions or concerns the HSRB may have with the data. Meeting minutes, reports, and past evaluations are provided on EPA's HSRB website: http://www.epa.gov/hsrb/ .

V: PURPOSE

The purpose of this WA is to provide a review of exposure studies to fulfill the requirements of HSRB and any other Executive Order or legislative requirement. The contractor shall: (1) perform statistical reviews of pesticide exposure studies submitted in order to expand and improve upon Agency surrogate exposure databases (e.g., industry task force data sources); (2) provide technical and statistical review support in reviewing materials (e.g., studies and protocols) from the Antimicrobial Exposure Assessment Task Force II (AEATF II), including presentations to the Human Studies Review Board (HSRB); (3) convene meetings, as requested by the Agency, to discuss and resolve issues related to the HSRB; and (4) provide other technical support in the general subject areas of statistics, exposure and risk assessment and pesticides to the Antimicrobials Division (AD) of EPA's Office of Pesticide Programs (OPP).

VI: GENERAL REQUIREMENTS

To perform Work Assignments under this contract, the contractor may require access to FIFRA Confidential Business Information (FIFRA CBI) submitted by pesticide registrants to EPA. Disclosure of FIFRA CBI to contractors is provided for under Section 10(e) of FIFRA and in 40 CFR 2.307. Consequently, the contractor must be cleared for access to FIFRA CBI and must control FIFRA CBI according to the requirements specified for contractors in the EPA

publication, "FIFRA Information Security Manual", dated July 1988. Access of the contractor to FIFRA CBI is intermittent and will not require allocation of office space. Identification of contractor personnel will be made by EPA while on site at EPA.

Control measures for protecting FIFRA CBI shall be in accord with the following sections of the Security Manual:

- "Disclosure of FIFRA CBI to contractors," Section 3;
- "Procedures for Gaining Access to FIFRA Sensitive Information," Section 4; and
- "Operational Procedures for Protecting FIFRA Sensitive Information," Section 5.

The contract, as written, shall incorporate certain clauses that describe actions to be taken by the contractor with regard to FIFRA sensitive information; these clauses are contained in **40 CFR 2.301 (h)(23)(ii)**, and are Exhibit 6 in the Security Manual.

In evaluating and performing services required under this Work Assignment (WA), the contractor shall submit all relevant information used in developing conclusions or options to the cognizant Work Assignment Manager (WAM) for all projects for review and approval.

All reports, drafts, papers etc. prepared by the contractor shall be submitted in draft form. The contractor shall submit the competed draft to the WAM for review and approval. The drafts submitted shall include copies of the literature cited or make reference to all citations in the document for WAM verification and approval.

When in attendance at meetings, the contractor's attendance shall be limited to that portion of the activity for which the contractor is required in order to meet the requirements of the SOW. The contractor personnel shall identify themselves as contractor personnel in all activities associated with work performed under the SOW, and in attendance at meetings in conjunction with activities with the SOW requirements.

Reports submitted by the contractor that contain recommendations to the Agency (which will be used by EPA personnel in developing policy), will explain and rank policy or action alternatives, if any; describe the procedures used to arrive at recommendations, summarize the substance of deliberation; report any dissenting views; list the sources relied upon; and make clear the methods and considerations upon which the recommendations are based.

VII: SCOPE OF WORK

The contractor shall supply the necessary labor, materials, equipment, services and facilities (except as otherwise specified) required for the performance of each work assignment. The scientific quality of assessments and reports and their timely preparation in accordance with negotiated schedules are of paramount importance in the performance of this contract. Consequently, the contractor shall have the necessary technical and scientific knowledge and

experience to work effectively from contract start-up and throughout the course of the contract. In addition, the contractor shall have a Quality Assurance (QA) / Quality Control (QC) program that maintains the quality of products. Performance of work under this WA will encompass tasks in Statistical Evaluation of Human Exposure.

VIII: HUMAN EXPOSURE SUPPORT

The contractor shall provide technical support for pesticide registration, reregistration and registration reviews, including the preparation of reports. The contractor shall: (1) perform technical reviews of pesticide exposure studies, and as per FQPA, also consider risks to infants and children from aggregate exposure; (2) expand and improve upon Agency surrogate exposure databases (e.g., industry task force data sources) and models; (3) provide technical support and in the integration and use of the Antimicrobial Exposure Joint Venture (AEJV); (4) provide technical and statistical review support in reviewing materials (e.g., protocols) from the AEATF, including presentations to the Human Studies Review Board (HSRB). (5) provide related technical support in the subject area of exposure/risk assessment and pesticides; and (7), as requested by the Agency, convene meetings, workshops and seminars, comprised of experts to discuss and resolve issues related to the above.

The contractor will conduct the above in accordance with this WA and by relying on the following:

- Series 875 Group A (Applicator exposure monitoring) and Series 875 Group B (Post-application exposures)
- Proposed Part 158 – Subpart W, Antimicrobials Data Requirements
- Exposure Factors Handbook (EPA Publication No. 600/P-95/002Fa,b,c)
- Standard Operating Procedures (SOPs) For Residential Exposure Assessments
- Exposure Assessment Guidelines (EPA Publication No. 600/2-92/001)

Task 1: Quick Response and Agency Interface Activities

The contractor shall provide quick turn-around support for special requests by EPA as defined in previous tasks. One task assignment form will be initiated for this action.

> The contractor shall provide support for special requests by EPA. This may include activities involving EPA's interface with other Governmental agencies, and any other quick-response requests from EPA to the extent that such requests are feasible and relate to this Statement of Work.

The contractor shall perform technical reviews of protocols and studies containing pesticide exposure and related data in support of registration and registration review activities, and shall review protocols submitted for such studies. Where appropriate, provide statistical review response based on EPA direction with respect to human exposure monitoring studies. These studies may include: (1) post-application exposure studies; (2) exposure monitoring data on the

subject chemical submitted by registrants on mixing/loading and application, and/or typical handling operations; (3) field exposure studies from the open scientific literature; and (4) exposure studies using surrogate pesticide chemical exposure data (e.g., proprietary industry task force data sources). Reviews of studies utilizing surrogate exposure data may be appropriate when the formulation type, application method, and use pattern are sufficiently similar to those of the chemical under review. Review of protocols for studies will evaluate adherence to Pesticide Assessment Guidelines, Series 875 - Occupational and Residential Exposure Test Guidelines, Group A & B along with recommendations for these types of studies by the SAP and HSRB.

For each assigned study, a written report shall be submitted by the contractor to the EPA Project Officer (PO) or Work Assignment Manager (WAM). Draft reports shall (1) document the contents of the studies; (2) note any discrepancies, inadequacies, and unresolved issues; (3) provide appropriate exposure calculations, correlations, and plots; and (4) provide a summary discussion and conclusions resulting from the review. The schedule for reports will be determined by the EPA WAM.

AD frequently needs to address questions on how best to implement the latest statistical techniques when addressing the exposure data in the risk assessments and how best to represent the sites for sample size calculations. We need to determine if the statistic evaluations of the data are sufficient for risk assessment or if the AEATF needs to do future improvements with respect to their data. AD could possibly also need to address past HSRB statistical design questions from the HSRB.

AD anticipates the need for quick response need for statistical support design and data evaluation advice for a number of past and future projects including:

- Statistical review support for the Paint Brush & Roller study.
- Statistical review support of Mop and Wipe Study
- Statistical review support for Pressure Treated Wood Studies
- Statistical review support for Antifoulant Paint Studies
- Statistical review support for the Solid Pour study.
- Statistical review support for AEATF pressure treated wood study.
- Statistical review support for an explanation of sample size/cluster/k-factor.
- Statistical review support for dermal loading.

Task 2: Data Analysis

The contractor shall review and analyze statistical methods for assessing unit exposures for dermal and inhalation monitoring data for pesticide applicators. Currently EPA expects to develop three or more task assignment forms (TAFs) for reviewing the data generated by the Antimicrobial Exposure Assessment Task Force (AEATF) for paint brush and roller, liquid pour, and pressure treated wood studies. EPA also anticipates that new studies will arrive from the AEATF and future TAFs will need to be initiated. Statistical analyses will include, but not

limited to, the AEATF's monitoring objective of a relative 3-fold accuracy (i.e., geometric mean, arithmetic mean, and 95th%tile be accurate within 3-fold with 95 percent confidence); reviewing sample size study design; calculating normalized unit exposures using and comparing empirical estimates, simple random sample estimates, as well as a hierarchical variance component modeling estimates; testing the exposure results for proportionality between exposure and pounds of active ingredient handled; and estimating the threshold of pounds a.i. where exposure is not underestimated.

When directed by EPA, the contractor shall:

(a) As directed, utilize all available Agency and non-Agency statistical/exposure models to determine exposures of pesticides from proposed or registered uses;

(c) As directed, review, examine, and compile all available Agency and non-Agency Statistical/exposure models for determining exposure of pesticides resulting from proposed or registered uses;

(d) As directed, assist the Agency in developing new, modified, or improved, statistical models or spreadsheets;

(e) Provide electronic copies of models, their manuals and literature search results about the use of each model. The contractor shall also be prepared to compare actual and estimated data from models, and provide a summary of the gaps between the two sets of data (if any), and provide recommendations on how to close the gaps; and

(f) Use variable data for running models; any estimated data should be verified with EPA before use.

IX. DELIVERABLES

All reports shall be provided in Microsoft Office Word format, both electronically and in paper copy. The contractor shall also provide disk copies of any appropriate spreadsheets or databases created under this work assignment, copies of models, literature and correspondence referenced in revised reports. In addition to Monthly Progress Reports, the Contractor shall meet the schedule listed below. The due dates are to be met unless otherwise specified by the Work Assignment Manager. Changes to the due dates listed below will involve consultations with the contractor and will consider the total estimated hours for each work assignment.

Deliverable	**Due Date**
Work Plan	15 days after WA received

Draft DER	15 days (or as specified in Task Assignment by PO or WAM)
Final DER	7 days after draft report submitted to contractor
Literature Search Listing	15 days after receiving the Task Assignment
Literature (hard copies)	As specified in Task Assignments by PO or WAM
Tasks and Subtasks	As specified in Task Assignments by PO or WAM (The due dates will vary depending on the discipline)

United States Environmental Protection Agency
Washington, DC 20460

Work Assignment

Work Assignment Number: 4-07

☒ Original ☐ Amendment Number:

Contract Number	Contract Period	Title of Work Assignment
EP-W-11-014	02/1/2015 to 01/31/2016 ☐ Base ☒ Option Period Number: IV	AD/PSB

Contractor: SUMMITEC CORPORATION

Specify Section and Paragraph of Contract SOW:

Purpose:
☒ Work Assignment Initiation ☐ Work Assignment Close-Out
☐ Work Assignment Amendment ☐ Incremental Funding
☐ Work Assignment Approval

Periods of Performance: From: Date of CO Signature To: 01/31/2016

Comments:
The estimated level of effort for this work assignment is 1,183 hours.

☐ Superfund

Accounting and Appropriations Data

☐ Non-Superfund

Line	DC (Max 6)	Budget/FYs (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 02/01/2015 To 01/31/2016	Cost/Fee	LOE
Previously Approved		
This Action		
Total		

Work Plan / Cost Estimate Approvals

Contractor WP Dated: Cost/Fee: LOE:

Cumulative Approved: Cost/Fee: LOE:

Work Assignment Manager Name: Wallace Powell
(Signature) (Date)
Branch/Mail Code: 7510P
Phone Number: (703) 308-6407
Fax Number:

Project Officer Name: LaTangila Edwards
(Signature) (Date)
Branch/Mail Code: 75092
Phone Number: (703) 305-7170
Fax Number:

Other Agency Official Name:
(Signature) (Date)
Branch/Mail Code:
Phone Number:
Fax Number:

Contracting Officer Name: Christine Edwards
Christine Edwards 2/26/2015
(Signature) (Date)
Branch/Mail Code: 3803R
Phone Number: (202) 564-2182
Fax Number:

Contractor Acknowledgement of Receipt and Approval of Workplan *(Signature and Title)*

Date

EPA Form 1900-69 (Rev. 07-95)

WA 4-07, AD/PSB
STATEMENT OF WORK
1/30/2015

I. TITLE

Antimicrobial Pesticide Registration: Evaluation of Product-Specific Data

II. WORK ASSIGNMENT MANAGER (WAM)

Primary:

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III. LEVEL OF EFFORT (LOE)

The estimated LOE for this WA is 1,183 hours.

IV. PERIOD OF PERFORMANCE

February 1, 2015 through January 31, 2016.

V. BACKGROUND

EPA's Office of Pesticide Programs (OPP), as required by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and the Federal Food, Drug and Cosmetic Act (FFDCA) as amended by the

Food Quality Protection Act (FQPA) of 1996, established procedures for the registration and reregistration of pesticide products. EPA has set forth and published data requirements and guidelines specifying the environmental resource information required supporting pesticide product registration and reregistration. Among these requirements are microbiological efficacy testing data, efficacy protocols submitted for approval prior to the conduct of efficacy testing, acute toxicity data, and product chemistry data. EPA's Antimicrobials Division (OPP/AD) is tasked with the evaluation of these types of data in support of registration (both initial and amended), re-registration and registration review. Under Contract EP-W-11-014, AD will order such evaluation work via this WA once the WA is issued by the Contracting Officer. All contractor and subcontractor personnel assigned to work on this WA must be CBI cleared.

This WA will be for conducting new work anticipated by EPA during Option Period 4. The contractor shall not knowingly duplicate work conducted under previous WAs or contracts. This new WA will provide for the review and evaluation of data from studies pertaining to efficacy, product chemistry and acute toxicology. OPP/AD will use the results of these contractor reviews and evaluations to support environmental and human exposure or hazard assessments used in making regulatory decisions, specifically those related to registration, re-registration and registration review and special review of antimicrobial pesticides.

VI. DESCRIPTION OF WORK

Under this WA, as the need arises, the WAM will assign any or all types of review work identified in the first paragraph of section V above through written technical direction. For the reviews assigned, the contractor shall:

- Review, evaluate, and assess data (1) to ensure that all information requirements are met, with respect to compliance with EPA guidelines and policies, and (2) to determine the adequacy of the study methods, data, and reporting, to support the claims and statements on the product label. To this end, the contractor shall review the efficacy-related claims and use-directions on the product label as they pertain to the study results, and provide comments as applicable;

- Identify unauthorized modifications to the approved efficacy test methods, or modifications to the methods in the latest approved OCSPP Series 870 *Health Effects* or Series 830 *Product Properties* or Series 810 *Product Performance* Test Guidelines;

- Determine if the efficacy performance standards of the OCSPP 810 Series guidelines and, where applicable, Subdivision G of the *Pesticide Assessment Guidelines*, and other AD approved efficacy protocols, are met; or if the product chemistry or acute toxicity results are sufficient;

- Determine if all items listed under 40 CFR 160.185 (*Reporting of Study Results*) are included for efficacy data, or if the Series 870 or 830 reporting requirements are included for product chemistry or acute toxicity data;

- Summarize findings using the efficacy Data Evaluation Report (DER) format or memorandum format, or using the DER/memorandum templates (to be provided to the contractor) for acute toxicity or product chemistry review; and

- Conduct reviews in accordance with all guidance received at meetings with the Agency; with all guidelines, templates, instructions, and resources indicated by the Agency; and with any other legitimate technical direction. (Refer to section VII below for further comments on technical direction and meetings.) The WAM may provide amended or additional DER or memorandum templates from time to time for the contractor to use in the situations for which they are applicable. The contractor is welcome to discuss and provide suggestions regarding the DER templates.

VII. COMMUNICATION AND TECHNICAL DIRECTION

The WAM will provide technical direction to the contractor on how to conduct reviews, as necessary. Further technical direction will be given from time to time in person, by telephone (followed by written summary), by email or other written means, and/or via meeting(s).

At any time, the contractor shall notify the Agency (Contracting Officer, Project Officer and/or WAM) of any concerns and/or issues related to data review, so that they may be remedied immediately.

The contractor may be called upon to meet with appropriate EPA staff in order to receive technical direction and clarification of review requirements, and to discuss and provide feedback regarding any issues of concern. Several such meetings/teleconferences may be called (by EPA) during the period of performance. The contractor's Work Assignment manager shall attend each meeting. The EPA WAM will specify which of the meetings shall also be attended by the contractor's lead reviewers and frequent reviewers. The contractor may be called upon to provide a summary of each meeting within a week after the meeting (if this task is deemed consistent with the Contract Statement of Work).

For any meetings located on-site at EPA, requirements for personal identity verification of contractor (including subcontractor) personnel while on-site at EPA shall be adhered to by both EPA and contractor personnel.

VIII. DELIVERABLES

As per the contract, the contractor shall provide the Agency with a work plan within 15 days of receipt of the WA. The Project Officer (PO) and WAM will review the work plan and provide the contractor with any changes/suggestions or revisions, in writing. Work plan approval/disapproval, and revision (if necessary), and the timelines involved, will proceed as stipulated in the contract. The work plan – together with Regulations, Contract, WA statement, and technical direction confirmed by written summary - will indicate the requirements and procedures for transfer and review of data packages and for completion of evaluation forms. The work plan should address (among other subjects as needed) the technical approach, resources, timeline, and due dates for all deliverables.

For most deliverables, the EPA WAM for this WA will assign a tentative due date to the task when its package and instruction is routed to the contractor. If, within three business days of such routing, the contractor expresses no concern regarding the due date, the date shall be deemed settled by tacit agreement. If the date remains unsettled after the three days, a new date not exceeding normal time frame will be assigned by mutual agreement. Each such deliverable shall be returned to the EPA WAM together with its Task Assignment Form and any disks and Data Package papers that had been routed.

The contractor shall deliver the findings of its reviews by preparing written reports and/or other documentation relating to the evaluations conducted. All work performed shall conform to EPA standards for QA/QC, DER formatting, and protocols submitted to and approved by OPP. All deliverables under this WA shall be submitted to the cognizant EPA WAM for review, approval, and forwarding. They shall be presented as electronic files: MS Word format; and on CD-ROM if physical delivery is requested. (If AD decides it needs printouts for certain types of deliverables, and/or a change in the type or number of disks or the electronic file type, the EPA WAM will inform the contractor by technical direction.)

The contractor shall provide each monthly progress report as per the contract. Among any other data required by contract, the report shall list each review action worked-on during the reporting period and shall indicate which actions were completed (finished and delivered) during the reporting period. For each reported action (be it pending or completed), the report shall list its Data Package identifier, its corresponding product registration no./file symbol (if any), its billable hours worked during the reporting period, and its Technical labor hours to date.

Content and format of the *monthly technical and financial progress report* must be intelligible and must be sufficient to support the Agency's review of invoicing, budget status, and technical progress. To this end, any new reporting needs found (i.e., any content or formatting beyond that of prior reports and beyond that of the above paragraph) may be requested by technical direction to the degree permissible under the contract.

IX. SCHEDULE OF DELIVERABLES

Deliverable	Schedule	Format/Distribution
Acknowledgement of Work Assignment (WA)	7 calendar days after WA is issued by Contracting Officer (CO)	Signed copy to CO
Work Plan (WP)	15 calendar days after WA is issued by CO	Email a copy to CO, PO, and the applicable WA COR (the WAM)
Quality Assurance Project Plan	Same as for the WP	Included with WP
Monthly report	As per the contract	Send to CO, copy or email to PO, email to WAM
Data review action	Due date assigned by WAM when packaged is routed.	MS Word format, delivered by electronic portal (or by CD if requested, 1 CD-ROM per action) to the WAM (and bundled with the action or Data Package if such had been routed).
Meeting summary (if requested)	1 week after the meeting	Email a copy to PO and WAM
Other	As per Contract	As per Contract